

## REMARKS

Claims 4, 22, 23, 25, 26, 38, 40, 44, 48, 80 and 81 are currently amended.

Claims 83-89 are new. No new matter is added.

### I. The Objection to claim 25

Claim 25 is currently amended. Reconsideration is urged.

### II. The rejection of claims 22, 23, 25, 26, 38, 40-48, 76-79, 81 and 82 as indefinite

Claims 22, 23, 25, 26, 38, 40, 44, 48 and 80 are currently amended.

Reconsideration is urged.

The Examiner has also rejected claims 38, 40-48, 76-82 as vague and indefinite in the recitation of "transferring-based protein". Applicants traverse this requirement.

The essential inquiry for determining indefiniteness is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness must be analyzed in light of the claim interpretation that would be given by one possessing the ordinary skill in the pertinent art at the time the invention was made. (M.P.E.P. 2173.02) One of ordinary skill in the art would certainly understand that the phrase "transferring-based protein" means transferrin or any other member of the transferrin family especially in light of the straightforward understanding transferrin-based proteins as expressly set out in the specification.

The Examiner's confusion is difficult to understand especially since the specification clearly sets out a definition of transferrin and transferring-based protein.

See e.g., page 53 lines 6-18.

In another particularly preferred embodiment the heterologous protein comprises the sequence of transferrin or a variant or fragment thereof. The term "transferrin" as used herein includes all members of the transferrin family (Testa, *Proteins of iron metabolism*, CRC Press, 2002; Harris & Aisen, *Iron carriers and iron proteins*, Vol. 5, Physical Bioinorganic Chemistry, VCH, 1991) and their derivatives, such as transferrin, mutant transferrins (Mason *et al*, 1993, *Biochemistry*, 32, 5472; Mason *et al*, 1998, *Biochem. J.*, 330(1), 35), truncated transferrins, transferrin lobes (Mason *et al*, 1996, *Protein Expr. Purif.*, 8, 119; Mason *et al*, 1991, *Protein Expr. Purif.*, 2, 214), lactoferrin, mutant lactoferrins, truncated lactoferrins, lactoferrin lobes or fusions of any of the above to other peptides, polypeptides or proteins (Shin *et al*, 1995, *Proc. Natl. Acad. Sci. USA*, 92, 2820; Ali *et al*, 1999, *J. Biol. Chem.*, 274, 24066; Mason *et al*, 2002, *Biochemistry*, 41, 9448).

See also page 66 lines 28-30 through page 67 lines 1-2:

By “transferrin-based protein” we mean transferrin or any other member of the transferrin family (e.g. lactoferrin), a variant or fragment thereof or a fusion protein comprising transferrin, a variant or fragment thereof, including the types described above. Thus the present invention also provides for the use of a recombinant PDI gene to increase the expression of a transferrin-based protein.

Accordingly, the specification makes clear that transferrin-based protein is not any amino acid. Reconsideration is urged in light of claimed language being clear.

The dependent claims are all clear for the reasons above.

### **III. The rejection of Claim 81 under 35 U.S.C. 101.**

Applicants have amended claim 81, as suggested by the Examiner, to include “isolated”. Reconsideration is urged.

### **IV. The rejection of claims 38, 40, 43, 45, 47 and 81 under 35 U.S.C. 102(b).**

The Examiner has rejected claims 38, 40, 43, 45, 47 and 81 as being anticipated by Shusta et al (Nature Biotechnol. 16, 773-777 (1998) (hereinafter referred to simply as “Shusta”).

The Examiner notes that “transferrin-based protein” or “a variant or fragment thereof or a fusion protein comprising transferrin, a variant or fragment thereof” encompass virtually any protein. Applicants traverse this rejection. Initially applicants note that claim 40 is currently amended to claim functional fragments. Reconsideration is urged.

Notwithstanding this amendment, claim 38 is not anticipated because the term “transferrin-based protein” is expressly defined in the specification and is clear as noted above. scFv of Shusta does not fall within this express definition. Accordingly, Shusta does not anticipate claims 38, 40, 43, 45, 47 and 81. Reconsideration is urged.

### **V. New Claims**

Claims 83-89 are new. No new matter is added. The transferrin sequence submitted herewith was well known at the time of filing. Should any additional fees be due the USPTO is authorized to charge the deposit Account of Novozymes North America, Inc. Deposit Account No. 50-1701.

**VI: SEQUENCE LISTING**

The electronic copy and the paper copy are the same. This submission contains no new matter which goes beyond the disclosure of the application as originally filed. No new matter is added. The transferrin sequence (SEQ ID NO:80) submitted herewith was well known at the time of filing.

**VII. Conclusion**

The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application. Should any additional fees be due the USPTO is authorized to charge the deposit account of Novozymes North America, Inc. *i.e.*, Deposit Account No. 50-1701.

Respectfully submitted,

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